UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,912	02/10/2000	Kimberly Kline	D6017CIP	4544

27851 7590 04/22/2002

BENJAMIN A. ADLER
8011 CANDLE LANE
HOUSTON, TX 77071

EXAMINER
NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/501,912	Kline et al.
Examiner	**Art Unit**
Patrick J. Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 25, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10 and 12-19* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10 and 12-19* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Part III DETAILED ACTION

1. This application is a continuation-in-part of 09/112,874, now abandoned, filed 7-9-98, which claims priority to 60/052,132, filed 7-10-97.

2. Claims 1-10 and 12-19 are pending.

3. Applicant's election with traverse of Group I, claims 1-10, 11-19 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the searches for the two groups would not be overly burdensome. This is not found persuasive for reasons set forth in Paper No. 7.

The requirement is still deemed proper and is therefore made FINAL.

4. It is noted the are nucleic acid sequences without SEQ ID NOS on page 25-26 of the specification. Applicant is required to amend the specification with the appropriate SEQ ID NO. found in the Paper Copy.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 6, 12, 13, 14, 17-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The monoclonal antibodies, hybridomas or phage display clones recited in claims 6, 12-14 and 17-19 are essential to the claimed invention. The reproduction of antibodies, hybridomas or clones from the disclosed techniques is an extremely unpredictable event. The monoclonal antibodies, hybridomas or phage display clones, disclosed in the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the monoclonal antibodies, hybridomas or phage display clones, and it is not apparent if the monoclonal antibodies, hybridomas or phage display clones are readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration

by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the monoclonal antibodies, hybridomas and phage display clones have been deposited under the Budapest Treaty and that the monoclonal antibodies, hybridomas and phage display clones will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

6. Claims 6, 12, 13, 14, 17-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of laboratory designations for the monoclonal antibodies, hybridomas and phage display clones makes the claims indefinite since they can change at any time and are somewhat arbitrary. Insertion of the ATCC number is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 5 and 15 are rejected under 35 U.S.C. § 102(e) as being anticipated by U. S. Patent No. 5, 686,600.

The `600 patent teaches a method of killing a pest with an antibody fragment attached to gelonin, wherein said antibody is specific for an antigenic epitope of a GI tract target cell (see abstract and column 3-4 in particular).

The prior art teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35

U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-10 and 16 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 5,686,600 (A), in view of U.S. Patent 5,837,242 (B) and U.S. Patent 5,870,852 (C).

The `600 patent has been discussed supra. Im addition the `600 patent teaches the use of scFv antibodies linked to toxins for the species specific killing of insects of the Order Hymenoptera. It is noted fire ants are of the Order Hymenoptera.

The claimed invention differs from the prior art teachings by the recitations of specifically killing fire ants and having two antibody fragments, one with specificity for the fire ant GI tract antigen bound to another antibody with specificity for a toxin. However, the `242 patent teaches the construction of scFv's (antibody fragments) and diabodies (two scFv's linked together) by a phage display technique that allows for easy isolation and that diabodies are particularly useful in therapies because they allow for one binding site for the toxin and one binding site for the targeted molecule. In addition the `242 patent teaches diabodies are very small and less immunogenic than full length $Fab_2$ molecules or antibodies. The `852 patent teaches that imported fire ants have rendered useless millions of acres of valuable property in the U.S. and that the primary problem in eradicating imported fire ants is that all currently used therapies kill non-specifically.

One of ordinary skill in the art at the time the invention was made would have been motivated to use scFv antibodies specific to insects and linked to toxins as taught by the '600 patent and eradicate fire ants because the '852 patent teaches they are a major problem but that all previously used therapies are non-specific and use diabodies using scFv's as taught by the '242 patent because phage display technique allows for easy isolation of the antibody molecule and that diabodies are particularly useful in therapies because they allow for one binding site for the toxin and one binding site for the targeted molecule and are less immunogenic than full length antibodies, as taught by the '242 patent. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.

9. If attempts to reach the examiner are unsuccessful, the

examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
April 21, 2002